IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Date: August 1, 2006

RICHARD R. HEUSER

Serial No. : 10/687,783 Our Docket No.: HEU 309

Filed : October 17, 2003 Group Art Unit: 3738

For : STENT WITH COVERING AND DIFFERENTIAL DILATION

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

I, Richard R. Heuser, MD, declare as follows:

1. I am the inventor of U.S. patent application Serial No. 10/687,783, filed October 17, 2003, and entitled STENT WITH COVERING AND DIFFERENTIAL DILATION.

2. I completed invention of the STENT WITH COVERING AND DIFFERENTIAL DILATION as recited in the claims of Ser. No. 10/687,783 in this country earlier than May 20, 1999. My conception and reduction to practice is demonstrated by confidential descriptions and drawings that I created. A copy of my descriptions and drawings, which I created and dated earlier than May 20, 1999 are attached as Exhibit 1. The dates in the descriptions and drawings, which have been redacted, are all earlier than May 20, 1999.

3. The descriptions and drawings show my invention, as recited in claim 8, of a stent comprising a wire mesh middle layer with an inner layer providing a flexible covering and an outer layer providing a flexible covering. The wire mesh layer is described in page 1

of Ex. A as "the metal" and the inner and outer layers are described as "the PTFE sealed on both sides of the metal." This invention is also referred to in page 1 of Ex. A as "a reversed sandwich," which is a contrasting reference to my invention of a stent having inner and outer wire mesh layers and a PTFE middle layer.

4. The stent of claim 8 is also shown in page 2 of Ex. A, in particular in the middle figure on that page depicting a stent comprising a wire mesh middle layer with an inner layer providing a flexible covering and an outer layer providing a flexible covering. I also described my invention prior to May 20, 1999 in page 3 of Ex. A, where the wire mesh middle layer is described as a "sinusoidal-ring design and 316L stainless steel segments." The inner and outer layers providing flexible coverings are described in the sentence: "The graft material is ePTFE that fully encapsulates the stent to provide up to 100% coverage."

5. My invention of the stent of claim 8 prior to May 20, 1999 is further shown in page 4 of Ex. A, where the wire mesh middle layer is described as "Stent: 316L Stainless Steel" and "Strut Design: Sinusoidal Ring with 3mm Length." The inner and outer layers are described as: "Graft: Expanded Polytetrafluoroethylene (ePTFE)."

6. I actually reduced this invention to practice prior to May 20, 1999. Actual stents in accordance with my descriptions and drawings were built and tested by a medical devices company called AVE, initially in animal studies prior to May 20, 1999. Photographs and descriptions of such stents are shown in Ex. B, pages 1 through 6. Page 1 of Ex. B is a single page collection of the slides that make up the remaining five pages of Ex. B. On page 1, a date, redacted, shows the slides were made before May 20, 1999 and depicted and described stents made before May 20, 1999.

7. Pages 2 and 3 of Ex. B are photographs of an example of the stent by itself (p. 2) and mounted on a balloon catheter (p. 3). Page 4 of Ex. B is a slide stating that evaluations of the stent in animals were under way, and that clinical studies (in humans) would be conducted in a month, redacted, that was prior to May 20, 1999.

8. Page 5 of Ex. B is a photograph of the stent mounted on a different balloon catheter and including additional description of some features of the stent. Page 6 further describes features of the stent.

9. In the subsequent clinical studies, several examples of stents in accordance with my descriptions and drawings were made for me and used experimentally in patients prior to May 20, 1999. Such stents included, in particular, stents comprising a wire mesh middle layer with an inner layer providing a flexible covering and an outer layer providing a flexible covering. These stents were successfully inserted in human blood vessels and expanded in place in the blood vessels and thus worked for their intended purpose.

10. I declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code. I understand that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

11/9/06

Date

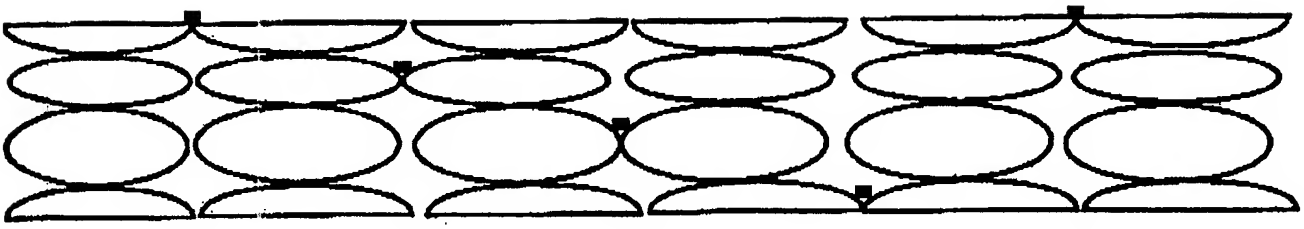
Richard R. Heuser, M.D.

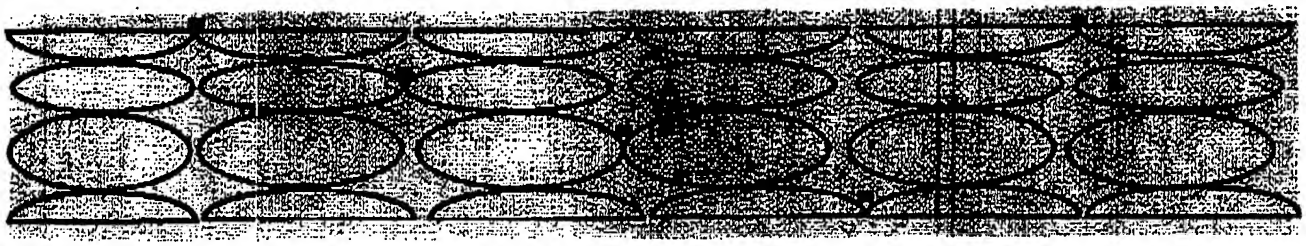
In Mid REDACTED came up with an idea, following this art REDACTED I drew a picture describing this idea. This idea is a reversed sandwich where the PTFE is outside the metal and the PTFE sealed on both sides of the metal.

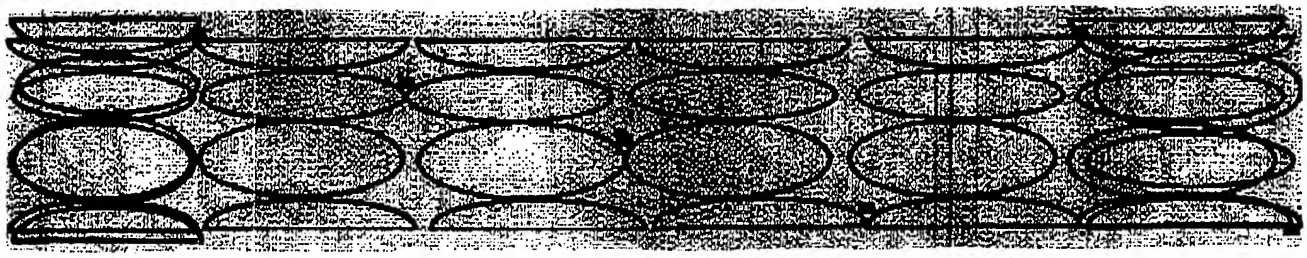
Richard R. Heuser, MD DATE: REDACTED Witness: Drew A. Krueger

Exhibit A
Serial No. 10/687,783
Page 1 of 4

1901 East Thomas Road • Suite 107 • Phoenix, Arizona 85016
Telephone: 602-234-0004 • Toll Free (888) 200-0348 • Fax: 602-234-0058







PRESENTED BY DR. RICHARD HEUSER
REDACTED

Description: AVE ePTFE Stent/Graft

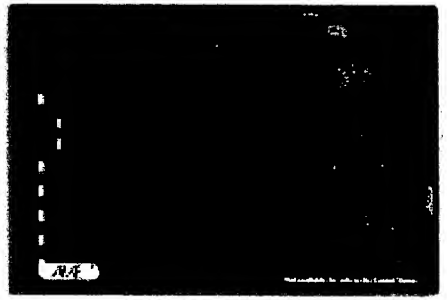
A balloon expandable stent/graft with a sinusoidal-ring design and 316L stainless steel segments. Individual segments are 3mm long and have an ellipto-rectangular cross-section with a thickness of 0.007". The graft material is ePTFE that fully encapsulates the stent to provide up to 100% coverage. Longitudinal flexibility is excellent and is slightly less than, but comparable to, the GFX. Shortening on expansion is less than 2%. Sheathless and pre-mounted, it has targeted diameters of 4.0mm-5.5mm in 0.5mm increments and lengths of 21mm, 30mm and 39mm. For a 5.5mm device the non-expanded profile target is 8F. Intended indication is for SVG Bypass.

AVE ePTFE Stent/Graft Technical Specifications

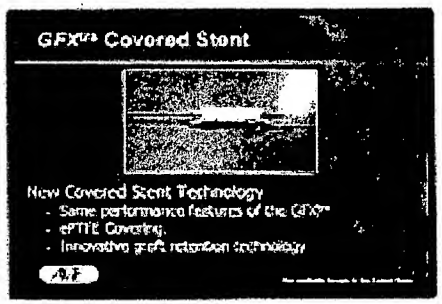
- Material Composition
  Graft: Expanded Polytetrafluoroethylene (ePTFE)

  Stent: 316L Stainless Steel
- Degree of Radio-opacity: Greater than GFX (Moderate)
- Surface Area: 100% (Can be Less with Added Macro-Porosity)
- Strut Design: Sinusoidal Ring with 3mm Length
- Strut Thickness: 0.007"
- Non-Expanded Profile: Target is 8F for a 5.5mm Device
- Longitudinal Flexibility: Less than but Comparable to GFX
- Shortening Upon Expansion: 2% or Less
- Targeted Expanded Diameters: 4.0mm, 4.5mm, 5.0mm and 5.5mm
- Targeted Lengths: 21mm, 30mm and 39mm
- Indication: SVG Bypass
- Delivery System: Balloon Expandable, Pre-Mounted With No External Sheath

2 SEP 10,1998



5 SEP 10,1998



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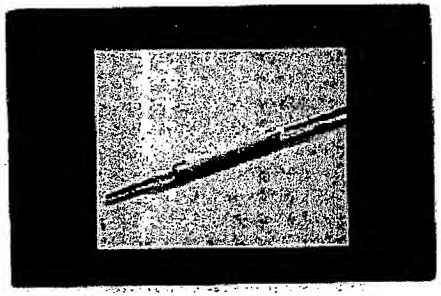
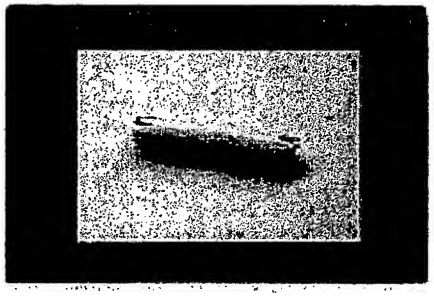


Paulson & Company
Photo/Graphic Communications
(602) 230-1550



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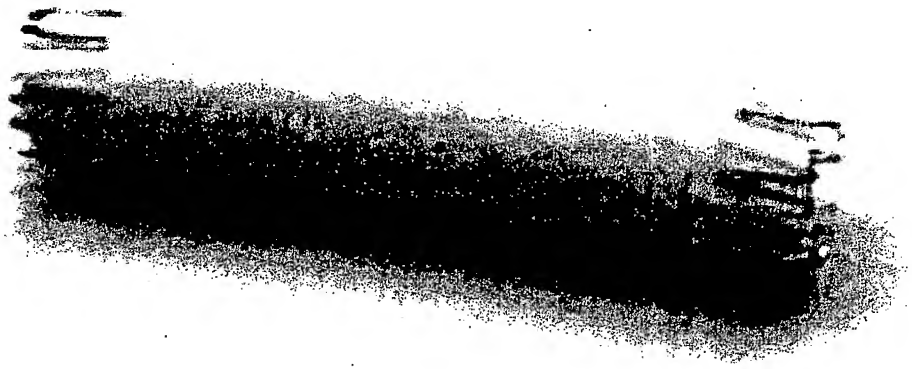
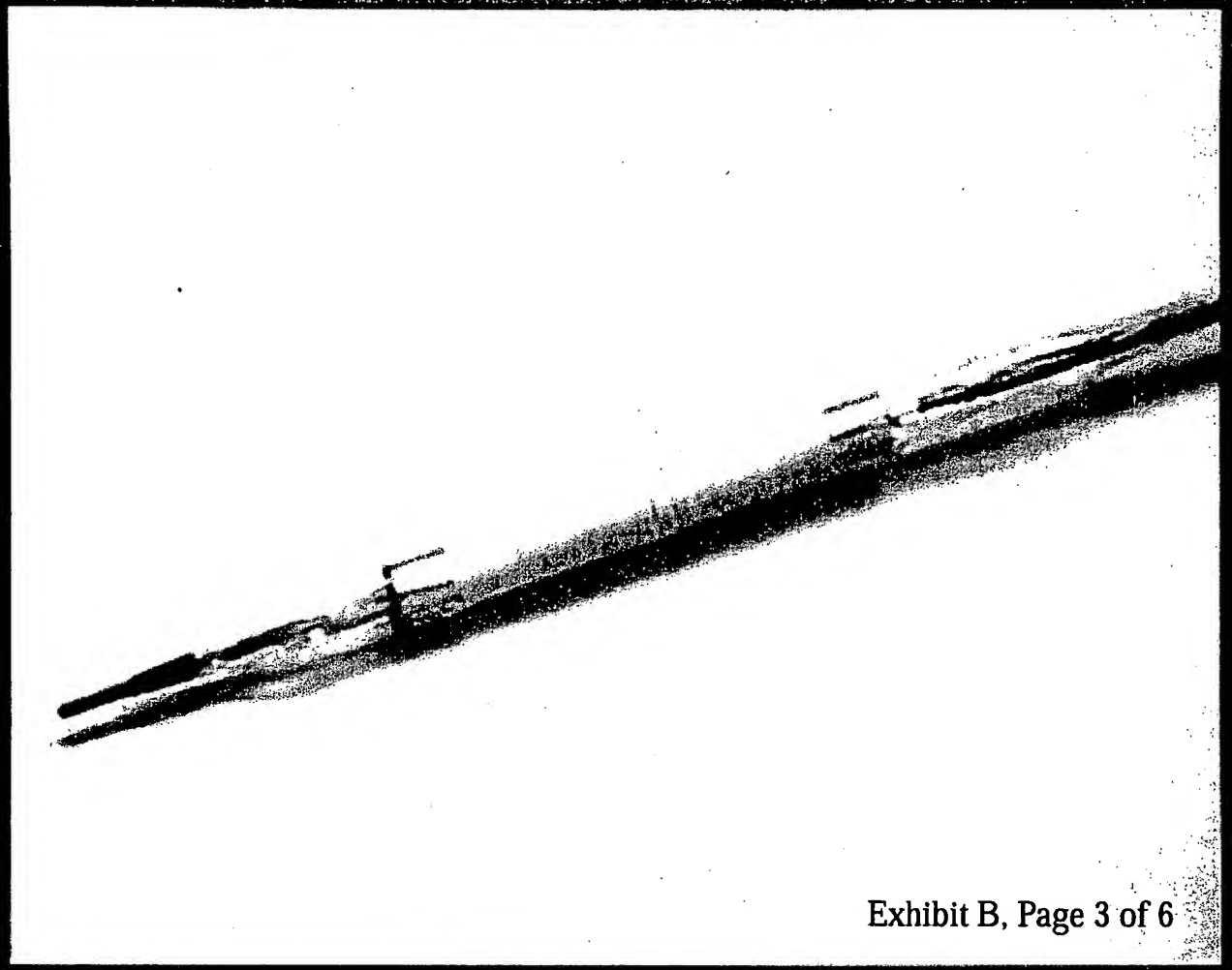
Photo/Graphic Communications
(602) 230-1550



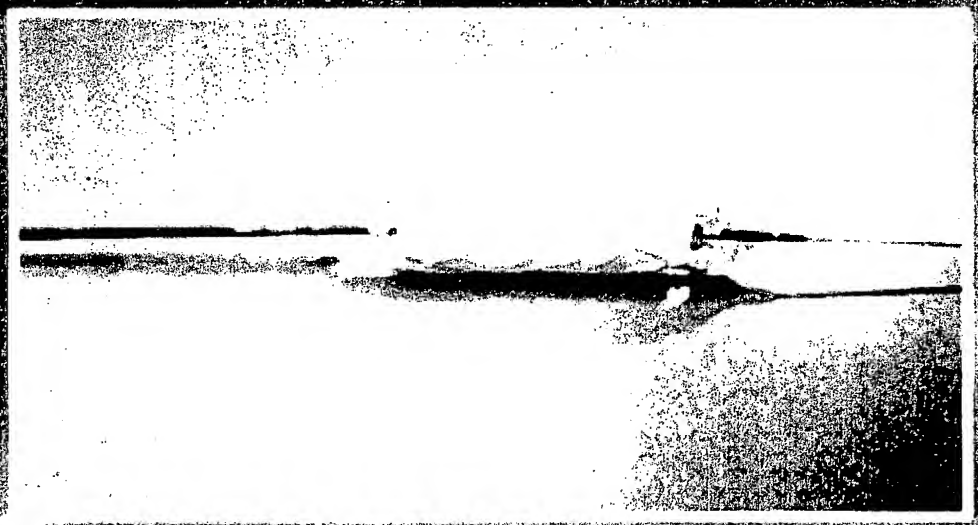


Status

- Final Evaluations In Process
- Initial Evaluations - October

AVE

GFX^{tra} Covered Stent

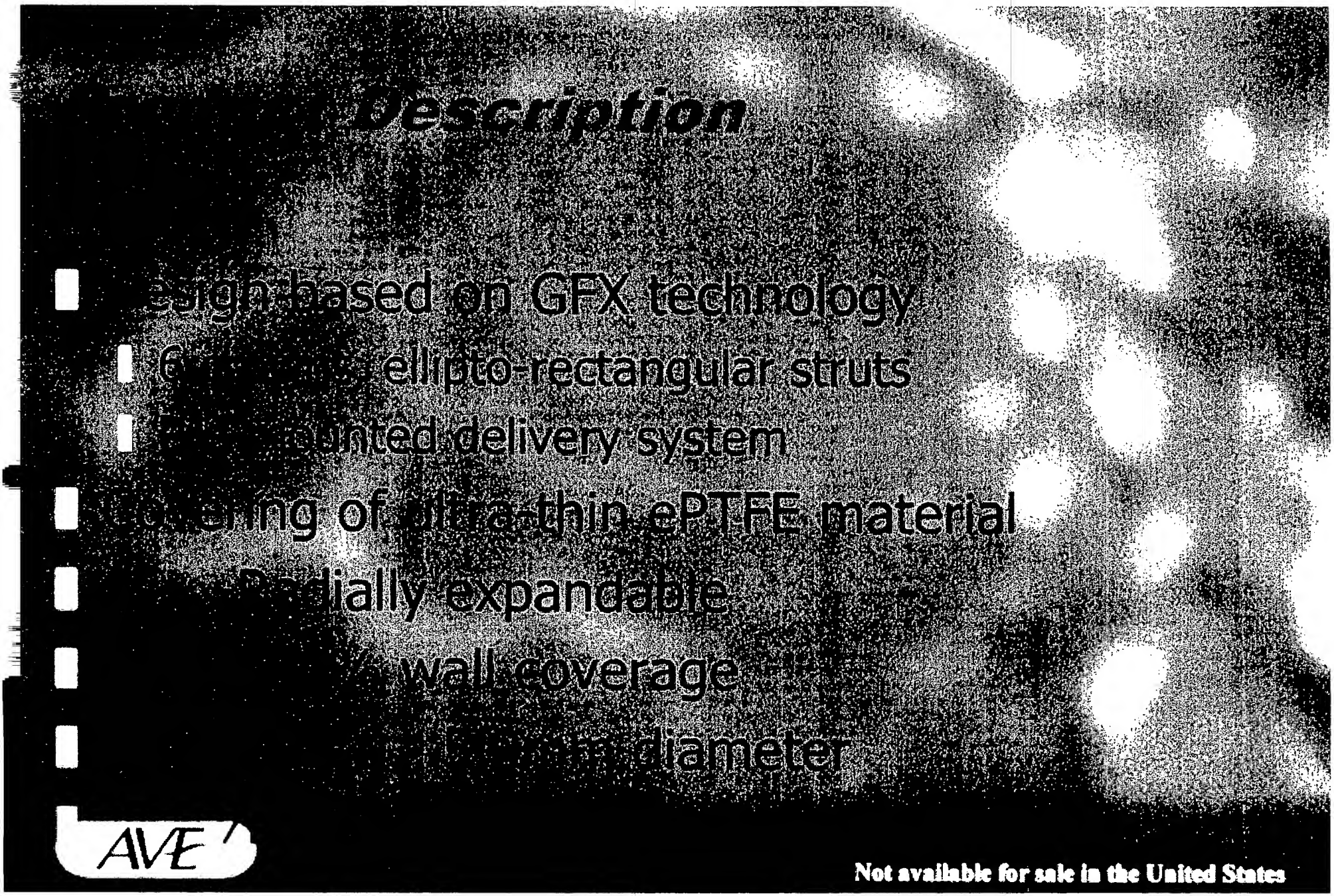


New Covered Stent Technology

- Same performance features of the GFX^{tra}
- ePTFE Covering
- Innovative graft retention technology

AVE

Not available for sale in the United States


Description
Design based on GFX technology
6 elipto-rectangular struts
mounted delivery system
covering of ultra-thin ePTFE material
radially expandable
wall coverage
diameter
AVE
Not available for sale in the United States